



Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection

Northeast Regional Office • 205B Lowell Street, Wilmington MA 01887 • 978-694-3200

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August 23, 2017

Mr. Richard Nill
Wyeth LLC / DBA Pfizer
One Burt Road
Andover, MA 01810

RE: ANDOVER
Transmittal No.: X271983
Application No.: NE-16-017
Class: *SM80-7*
FMF No.: 130125
AIR QUALITY PLAN APPROVAL

Dear Mr. Nill:

The Massachusetts Department of Environmental Protection (“MassDEP”), Bureau of Air and Waste, has reviewed your Limited Plan Application (“Application”) listed above. This Application concerns the proposed construction of a new building (“Building E”) which will contain five new manufacturing suites at your existing manufacturing facility located at One Burt Road in Andover, Massachusetts (“Facility”).

This Application was submitted in accordance with 310 CMR 7.02 Plan Approval and Emission Limitations as contained in 310 CMR 7.00 “Air Pollution Control” regulations adopted by MassDEP pursuant to the authority granted by Massachusetts General Laws, Chapter 111, Section 142 A-O, Chapter 21C, Section 4 and 6, and Chapter 21E, Section 6. MassDEP’s review of your Application has been limited to air pollution control regulation compliance and does not relieve you of the obligation to comply with any other regulatory requirements.

MassDEP has determined that the Application is administratively and technically complete and that the Application is in conformance with the Air Pollution Control regulations and current air pollution control engineering practice, and hereby grants this **Plan Approval** for said Application, as submitted, subject to the conditions listed below.

Please review the entire Plan Approval, as it stipulates the conditions with which the Facility owner/operator (“Permittee”) must comply in order for the Facility to be operated in compliance with this Plan Approval.

This information is available in alternate format. Contact Michelle Waters-Ekanem, Director of Diversity/Civil Rights at 617-292-5751.

TTY# MassRelay Service 1-800-439-2370

MassDEP Website: www.mass.gov/dep

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1. DESCRIPTION OF FACILITY AND APPLICATION

Pfizer (“Permittee”) is an existing facility located at One Burt Road in Andover, MA which conducts commercial and clinical manufacturing of biopharmaceuticals as well as research and development in several existing buildings. The Permittee proposes to construct a new building (“Building E”) which will house five new manufacturing suites and will contain a mix of stainless and disposable vessels. The manufacturing equipment will also include portable and non-portable buffer tanks, pressure vessels of varying sizes, fume hoods, and associated exhaust fans.

Building E will consist primarily of single-use disposable technology using volatile organic compounds (VOC) such as ethanol and acetic acid in its manufacturing operations, and several VOC containing cleaning agents which will be used for surface disinfection. Single-use disposable technology significantly minimizes any fugitive VOC emissions from the manufacturing operations and significantly reduces surface disinfection operations since the process is self-contained and the vessel does not need to be cleaned after it has served its useful life. Process emission factors, as determined from other similar manufacturing and surface disinfection operations, are estimated to be a 25% loss for ethanol and a 10% loss for acetic acid in the manufacturing operations while 100% of the surface disinfection chemicals are assumed to be evaporated. The VOC and hazardous air pollutant emissions (HAPs) from the new Building E will be monitored and recorded under the facility assigned Emission Unit No. of ACMF-01.

VOC used for surface disinfection will be stored in closed containers when not in use, and excess material will be collected for proper disposal. Cleaning rags or wipes associated with surface disinfection operations will be placed in covered containers and collected for proper disposal or recycling.

The purpose of this plan application is to establish VOC emission limitations for the new Building E, the Permittee is not proposing to increase its existing facility-wide VOC emission limitation of 49 tons per year as stated in the CONDITIONAL APPROVAL of Plan Application No. MBR-01-COM-053 which was issued on February 28, 2002.

2. EMISSION UNIT (EU) IDENTIFICATION

Each Emission Unit (EU) identified in Table 1 is subject to and regulated by this Plan Approval:

| Table 1 | | | |
|---------|---|-------------------------------|--------------------------------|
| EU | Description | Design Capacity | Pollution Control Device (PCD) |
| ACMF-01 | Biopharmaceutical manufacturing operations and associated surface disinfection operations from Building E | Twelve (12) 100-liter vessels | None |

Table 1 Key:

EU = Emission Unit Number

PCD = Pollution Control Device

3. APPLICABLE REQUIREMENTS

A. OPERATIONAL, PRODUCTION and EMISSION LIMITS

The Permittee is subject to, and shall not exceed the Operational, Production, and Emission Limits as contained in Table 2:

| Table 2 | | | |
|---------|--------------------------------|-----------------|----------------------|
| EU# | Operational / Production Limit | Air Contaminant | Emission Limit |
| ACMF-01 | None | VOC | 0.5 TPM 2.0 TPY |
| | | Total HAPs | 0.03 TPM 0.10 TPY |

Table 2 Key:

EU# = Emission Unit Number
 VOC = Volatile Organic Compounds
 Total HAPs = Total Hazardous Air Pollutants
 TPY = tons per consecutive 12-month period
 TPM = tons per month

B. COMPLIANCE DEMONSTRATION

The Permittee is subject to, and shall comply with, the monitoring, testing, record keeping, and reporting requirements as contained in Tables 3, 4, and 5:

| Table 3 | |
|----------------|--|
| EU# | Monitoring and Testing Requirements |
| ACMF-01 | 1. The Permittee shall monitor material usage on a monthly basis such that records can be maintained of the emissions of VOCs and total HAPs to determine compliance status with the emission limits contained in Table 2 above. |
| | 2. The Permittee shall monitor operations on a monthly basis such that records can be maintained to determine the compliance status of the Operational Limits detailed in Table 2 above. |
| Facility-wide | 3. The Permittee shall monitor all operations to ensure sufficient information is available to comply with 310 CMR 7.12 Source Registration. |
| | 4. If and when MassDEP requires it, the Permittee shall conduct emission testing in accordance with USEPA Reference Test Methods and Regulation 310 CMR 7.13 |

Table 3 Key:

EU# = Emission Unit Number
 USEPA = United States Environmental Protection Agency
 MassDEP = Massachusetts Department of Environmental Protection

VOC = Volatile Organic Compounds
 HAPs = Hazardous Air Pollutants
 CMR = Code of Massachusetts Regulations

| Table 4 | |
|---------------|---|
| EU# | Record Keeping Requirements |
| ACMF-01 | 1. The Permittee shall maintain adequate records on-site to demonstrate compliance with all operational, production, and emission limits contained in Table 2 above. Records shall include the monthly material usage records and all other records used to determine the actual emissions of air contaminant(s) emitted for each calendar month and for each consecutive twelve month period (current month plus prior eleven months). These records shall be compiled no later than the 15 th day following each month. An electronic version of the MassDEP approved record keeping form, in Microsoft Excel format, can be downloaded at http://www.mass.gov/eea/agencies/massdep/air/approvals/limited-emissions-record-keeping-and-reporting.html#WorkbookforReportingOn-SiteRecordKeeping . |
| | 2. The Permittee shall maintain records of monitoring and testing as required by Table 3. |
| | 3. The Permittee shall maintain a copy of this Plan Approval, underlying Application and the most up-to-date SOMP for the EUs approved herein on-site. |
| | 4. The Permittee shall maintain a record of routine maintenance activities performed on the approved EUs and monitoring equipment. The records shall include, at a minimum, the type or a description of the maintenance performed and the date and time the work was completed. |
| Facility-wide | 5. The Permittee shall maintain records to ensure sufficient information is available to comply with 310 CMR 7.12 Source Registration. |
| | 6. The Permittee shall maintain records required by this Plan Approval on-site for a minimum of five (5) years. |
| | 7. The Permittee shall make records required by this Plan Approval available to MassDEP and USEPA personnel upon request. |

Table 4 Key:

EU# = Emission Unit Number
 SOMP = Standard Operating and Maintenance
 Procedure
 MassDEP = Massachusetts Department of
 Environmental Protection

CMR = Code of Massachusetts Regulations
 USEPA = United States Environmental Protection
 Agency

| Table 5 | |
|----------------|---|
| EU# | Reporting Requirements |
| Facility-wide | 1. The Permittee shall submit to MassDEP all information required by this Plan Approval over the signature of a “Responsible Official” as defined in 310 CMR 7.00 and shall include the Certification statement as provided in 310 CMR 7.01(2)(c). |
| | 2. The Permittee shall notify the Northeast Regional Office of MassDEP, BAW Permit Chief by telephone: (978-694-3200), email at nero.air@state.ma.us or fax 978-694-3499, as soon as possible, but no later than three (3) business days after discovery of an exceedance(s) of Table 2 requirements. A written report shall be submitted to the Compliance and Enforcement Chief at MassDEP within ten (10) business days thereafter and shall include: identification of exceedance(s), duration of exceedance(s), reason for the exceedance(s), corrective actions taken, and action plan to prevent future exceedance(s). |
| | 3. The Permittee shall provide a copy to MassDEP of any record required to be maintained by this Plan Approval within 30 days from MassDEP’s request. |
| | 4. The Permittee shall submit to MassDEP for approval a stack emission pretest protocol, at least 60 days prior to emission testing, for emission testing as defined in Table 3 Monitoring and Testing Requirements. |
| | 5. The Permittee shall submit to MassDEP a final stack emission test results report, within 45 days after emission testing, for emission testing as defined in Table 3 Monitoring and Testing Requirements. |

Table 5 Key:

EU# = Emission Unit Number
 CMR = Code of Massachusetts Regulations
 MassDEP = Massachusetts Department of
 Environmental Protection
 BAW = Bureau of Air and Waste

4. SPECIAL TERMS AND CONDITIONS

The Permittee is subject to, and shall comply with, the following special terms and conditions:

- A. The Permittee is subject to and shall comply with the Special Terms and Conditions as contained in Table 6:

| Table 6 | |
|----------------|---|
| EU# | Special Terms and Conditions |
| ACMF-01 | 1. The Permittee shall follow the Standard Operating and Maintenance Procedures (SOMPs) for the subject emission units so as to maintain its efficient operation and to minimize both VOC and HAPs emissions. |
| | 2. All cleaning rags used in conjunction with the cleaning solutions shall be placed in tightly covered containers when not in use, and shall be collected for proper recycling or disposal. |
| | 3. All VOC containing and/or HAPs containing materials, such as solvents and clean-up solutions, shall be transported and stored in tightly covered containers. Any emissions associated with solvent and /or cleanup solutions shall be included in the monthly and 12 month rolling emissions calculations to determine the compliance status with emission limits contained in Table 2 above. |
| Facility-wide | 4. The facility-wide emissions of NO _x and VOC shall not exceed 49 tons, respectively per rolling 12-month calendar period as stated in the CONDITIONAL APPROVAL issued for Application No. MBR-01-COM-053 on February 28, 2002. |
| | 5. Any prior Plan Approvals issued under 310 CMR 7.02 shall remain in effect unless specifically changed or superseded by this Plan Approval. The Facility shall not exceed the emission limits and shall comply with approved conditions specified in the prior Plan Approval(s) unless specifically altered by this Plan Approval. |
| | 6. The Permittee shall submit a Consolidation of Previously Issued Plan Approvals (BWP AQ 33) to the Northeast Regional Office of MassDEP, attention BAW Permit Chief by no later than March 30, 2018 in order to consolidate this Plan Approval with all other applicable Approvals issued to Genetics Institute at One Burt Road, Andover, Massachusetts such as the CONDITIONAL APPROVAL for Application No. MBR-01-COM-053. |

Table 6 Key:

EU = Emission Unit Number
 NO_x = Nitrogen Oxides
 VOC = Volatile Organic Compounds
 HAPs = Hazardous Air Pollutants
 CMR = Code of Massachusetts Regulations
 No. = number

- B. The Permittee shall install and use an exhaust stack, as required in Table 7, on each of the Emission Units that is consistent with good air pollution control engineering practice and that discharges so as to not cause or contribute to a condition of air pollution. Each exhaust stack shall be configured to discharge the gases vertically and shall not be equipped with any part or device that restricts the vertical exhaust flow of the emitted gases, including but not limited to rain protection devices known as “shanty caps” and “egg beaters.”

- C. The Permittee shall install and utilize exhaust stacks with the following parameters, as contained in Table 7, for the Emission Units that are regulated by this Plan Approval:

| Table 7 | | | | |
|----------------|---|--|--|--|
| EU# | Stack Height Above Ground (feet) | Stack Inside Exit Dimensions (feet) | Stack Gas Exit Velocity Range (feet per second) | Stack Gas Exit Temperature Range (°F) |
| ACMF-01 | N/A | N/A | N/A | N/A |

Table 7 Key:

EU# = Emission Unit Number

°F = Degree Fahrenheit

N/A = Not applicable

Table 7 Notes: ACMF-01 will vent to a large number of general ventilation and exhaust points. To the extent that any exhaust stacks are installed, they shall comply with good air pollution control engineering practices and Paragraph 4.B. above.

5. GENERAL CONDITIONS

The Permittee is subject to, and shall comply with, the following general conditions:

- A. Pursuant to 310 CMR 7.01, 7.02, 7.09 and 7.10, should any nuisance condition(s), including but not limited to smoke, dust, odor or noise, occur as the result of the operation of the Facility, then the Permittee shall immediately take appropriate steps including shutdown, if necessary, to abate said nuisance condition(s).
- B. If asbestos remediation/removal will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that all removal/remediation of asbestos shall be done in accordance with 310 CMR 7.15 in its entirety and 310 CMR 4.00.
- C. If construction or demolition of an industrial, commercial or institutional building will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that said construction or demolition shall be done in accordance with 310 CMR 7.09(2) and 310 CMR 4.00.

- D. Pursuant to 310 CMR 7.01(2)(b) and 7.02(7)(b), the Permittee shall allow MassDEP and / or USEPA personnel access to the Facility, buildings, and all pertinent records for the purpose of making inspections and surveys, collecting samples, obtaining data, and reviewing records.
- E. This Plan Approval does not negate the responsibility of the Permittee to comply with any other applicable Federal, State, or local regulations now or in the future.
- F. Should there be any differences between the Application and this Plan Approval, the Plan Approval shall govern.
- G. Pursuant to 310 CMR 7.02(3)(k), MassDEP may revoke this Plan Approval if the construction work is not commenced within two years from the date of issuance of this Plan Approval, or if the construction work is suspended for one year or more.
- H. This Plan Approval may be suspended, modified, or revoked by MassDEP if MassDEP determines that any condition or part of this Plan Approval is being violated.
- I. This Plan Approval may be modified or amended when in the opinion of MassDEP such is necessary or appropriate to clarify the Plan Approval conditions or after consideration of a written request by the Permittee to amend the Plan Approval conditions.
- J. Pursuant to 310 CMR 7.01(3) and 7.02(3)(f), the Permittee shall comply with all conditions contained in this Plan Approval. Should there be any differences between provisions contained in the General Conditions and provisions contained elsewhere in the Plan Approval, the latter shall govern.

6. MASSACHUSETTS ENVIRONMENTAL POLICY ACT

MassDEP has determined that the filing of an Environmental Notification Form (ENF) with the Secretary of Energy & Environmental Affairs, for air quality control purposes, was not required prior to this action by MassDEP. Notwithstanding this determination, the Massachusetts Environmental Policy Act (MEPA) and 301 CMR 11.00, Section 11.04, provide certain “Fail-Safe Provisions,” which allow the Secretary to require the filing of an ENF and/or an Environmental Impact Report (EIR) at a later time.

7. APPEAL PROCESS

This Plan Approval is an action of MassDEP. If you are aggrieved by this action, you may request an adjudicatory hearing. A request for a hearing must be made in writing and postmarked within twenty-one (21) days of the date of issuance of this Plan Approval.

Under 310 CMR 1.01(6)(b), the request must state clearly and concisely the facts, which are the grounds for the request, and the relief sought. Additionally, the request must state why the Plan Approval is not consistent with applicable laws and regulations.

The hearing request along with a valid check payable to the Commonwealth of Massachusetts in the amount of one hundred dollars (\$100.00) must be mailed to:

Commonwealth of Massachusetts
Department of Environmental Protection
P.O. Box 4062
Boston, MA 02211

This request will be dismissed if the filing fee is not paid, unless the appellant is exempt or granted a waiver as described below. The filing fee is not required if the appellant is a city or town (or municipal agency), county, or district of the Commonwealth of Massachusetts, or a municipal housing authority.

MassDEP may waive the adjudicatory hearing-filing fee for a person who shows that paying the fee will create an undue financial hardship. A person seeking a waiver must file, together with the hearing request as provided above, an affidavit setting forth the facts believed to support the claim of undue financial hardship.

Should you have any questions concerning this Plan Approval, please contact Mr. Mun Wong by telephone at 978-694-3286, or in writing at the letterhead address.

Sincerely,

This final document copy is being provided to you electronically by the
Department of Environmental Protection. A signed copy of this document
is on file at the DEP office listed on the letterhead.

Edward J. Braczyk
Acting Permit Chief
Bureau of Air and Waste

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Mun S. Wong
Environmental Engineer

cc: Board of Health, 36 Bartlet Street, Andover, MA 01810
Fire Headquarters, 32 North Main Street, Andover, MA 01810
MassDEP/Boston - Yi Tian (e-copy)
MassDEP/NERO - Ed Braczyk (e-copy)
MassDEP/NERO - Martha Bolis, Mary Persky (hard copy & e-copy)
IRWIN Engineers, Inc., 33 West Central Street, Natick, MA 01760 ATTN: Mr. J. Andrew Irwin

Susan Ruch, Deputy Regional Director, MassDEP NERO/BAW
Email: susan.ruch@state.ma.us